Applicant: Lanphere et al. Attorney's Docket No.: 01194-465001 / 03-347

Serial No.: 10/637,130 Filed: August 8, 2003

Page : 3 of 6

## **REMARKS**

Applicants amended the specification to disclaim priority to U.S. Patent Application Serial No. 10/215,594, and U.S. Patent Application Serial No. 10/615,276. Applicants also amended the specification to maintain the incorporation by reference of these applications.

The Examiner did not initial all the references in the information disclosure statement filed November 07, 2005, asserting that "[s]ome of the references cited have not been considered in the merits because they appear to be irrelevant to the claimed subject matter." However, Applicants believe that the information disclosure statement complies with 37 CFR §§ 1.97 and 1.98. Accordingly, Applicants believe that it is the Examiner's obligation to properly consider the references listed in the 1449 form submitted with the information disclosure statement, and to indicate as much by returning to Applicants a copy of the 1449 form initialed by the Examiner, demonstrating such consideration by the Examiner. (See, MPEP § 609.05(b).)

The Examiner rejected claims 1, 2, 5-8, 11-20, 22-30 and 41-58 under 35 U.S.C. §102(b) as being anticipated by Mangin, WO 01/66016 ("Mangin") or under 35 U.S.C. §103(a) as being unpatentable over Mangin. These claims cover particles with an average pore size in an interior region that is greater than an average pore size at a surface region. Mangin does not disclose or suggest such particles. Rather, Mangin simply discloses particles having one or more voids for containing gas or microbubbles of gas such that the particles are visible under ultrasound. (See, e.g., Mangin, page 6, lines 6-8.)

In making the rejection, the Examiner states that the claimed subject matter is "shown in figures 1A and 1B and reinforced by the method disclosed at page 8, lines 17-25 of the Mangin publication." (Office Action at page 3.) In other words, the Examiner is relying on what is alleged to be inherently disclosed by Mangin to reject the claims. As stated by the United States Court of Appeals for the Federal Circuit <u>Electro Sys. S.A. v. Cooper Life Sciences</u>, 34 F.3d 1048, 1052 (Fed. Cir. 1994):

The mere fact that a thing *may result* from a given set of circumstances is insufficient to prove anticipation. (citations omitted; emphasis original).

Applicant: Lanphere et al. Attorney's Docket No.: 01194-465001 / 03-347

Serial No.: 10/637,130 Filed: August 8, 2003

Page : 4 of 6

Rather, one asserting that a reference inherently discloses certain subject matter must prove that the features are:

necessarily present [in the prior art reference] and that it would be so recognized by persons of ordinary skill. (<u>Id.</u>)

Here, the Examiner has not satisfied the requisite legal standard because the Examiner has not established that a person of ordinary skill in the art would recognize that Mangin necessarily discloses particles wherein the average pore size in the interior region is greater than the average pore size at the surface region.

Regarding Figs. 1A and 1B of Mangin, Applicants believe that the Examiner is misinterpreting these figures. Fig. 1A shows the surface of Mangin's particle, and Fig. 1B shows a cross-sectional view of Mangin's particle. Because the diameters of Figs. 1A and 1B appear to be substantially identical, Applicants believe that Fig. 1B is a cross-section through the middle of Mangin's particle, thereby showing pores in the interior region of Mangin's particle. It is apparent that Fig. 1A shows more large pores than Fig. 1B. The only reasonable conclusion to be drawn from this is that Fig. 1A has an average pore size that is greater than the average pore size of Fig. 1B. Thus, Mangin discloses a particle having a surface region with pores having an average size that is greater than the average size of the pores in the interior of Mangin's particle. In the Office Action, the Examiner states:

[F]rom the cross-section as shown in figure 1B, it can be extrapolated that the interior, which includes multiple of such cross sections, would have at least twice as larger pores as the number of larger pores on the surface. (Office Action, p. 3.)

Applicants find this statement confusing and illogical. As noted above, Fig. 1B appears to be a cross-section through the middle of Mangin's particle. While Applicants appreciate that there are theoretically an infinite number of cross-sections through the middle of Mangin's particle, Applicants cannot understand the Examiner's comment that one can apparently "extrapolate"

Applicant: Lanphere et al. Attorney's Docket No.: 01194-465001 / 03-347

Serial No.: 10/637,130 Filed: August 8, 2003

Page : 5 of 6

based on these cross-sections to reach the conclusion that there are more larger pores in the interior of Mangin's particle than on the surface of Mangin's particle. Perhaps, under the Examiner's approach, the Examiner is failing to appreciate that a given pore would be shown in many of the cross-sections. In any event, Applicants do not agree with the Examiner's conclusion and request that the Examiner explain in a more understandable fashion exactly how his extrapolation results in his conclusion.

Regarding Mangin's method disclosed at page 8, lines 17-25, which involves leaching out soluble material from the polymer spheres formed from emulsification, the Examiner has provided no basis for his conclusion that the process would inherently result in a particle with an average pore size in an interior region that is greater than an average pore size at a surface region. To the contrary, as would be understood by one skilled in the art, Mangin's method would not necessarily result in such a particle.

Nor is there any suggestion to modify Mangin to provide the particles covered by claims 1, 2, 5-8, 11-20, 22-30, and 41-58. For example, according to Mangin his particle satisfies his perceived need. (See, e.g., Mangin at Abstract and page 4, lines 1-page, 5, line 31.) After reading this, a person of ordinary skill in the art would not have been motivated to modify Mangin's particles to provide the particles covered by these claims. Applicants therefore request reconsideration and withdrawal of the rejections under 35 U.S.C. §§102(b) and 103(a).

Please apply any other charges or credits to deposit account 06-1050.

Applicant: Lanphere et al. Serial No.: 10/637,130 Filed: August 8, 2003

Page : 6 of 6

Attorney's Docket No.: 01194-465001 / 03-347

Respectfully submitted,

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